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(71) Applicant *(for all designated States except US)*: **AORTECH INTERNATIONAL PLC** [GB/GB]; Phoenix Crescent Business Park, Bellshill ML4 3NJ (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **BEITH, Jason** [GB/US]; Edwards Lifescience, On edwards Way, Irvine, CA 92614 (US).

(74) Agent: **MURGITROYD & COMPANY**; Scotland House, 165-169 Scotland Street, Glasgow G5 8PL (GB).

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(54) Title: BLOOD REGULATION DEVICE

(57) Abstract: The present invention relates to a cardiovascular stent including a generally tubular body and a synthetic valve capable of moving from a first open position to a second closed position wherein, in use, the stent is located between a first compartment and a second compartment and movement of blood in one direction causes the valve to move to an open position and movement of blood in a second opposite direction causes the valve to move to a closed position. In particular a stent is provided to connect the left ventricle of the heart to a coronary artery which allows blood to flow through the stent from the left ventricle of the heart into a coronary artery, but minimises reflux of blood from the coronary artery to the left ventricle of the heart.

"Blood Regulation Device"

The present invention relates to stents for connecting a first compartment to a second compartment. In particular, the invention relates to cardiovascular stents e.g. for connection of the left ventricle of the heart to a coronary artery.

Coronary artery disease is a major problem thoughout the world, particularly in Western society. Coronary arteries, as well as other blood vessels, can become clogged with plaque, impairing the efficiency of the heart's pumping action. This can lead to heart attacks, angina and death.

A number of methods are used to treat clogged coronary arteries such as bypass operations or balloon angioplasty.

In bypass operations one or more venous segments are inserted between the aorta and the coronary arteries to bypass the blocked portion of the coronary artery such that an unobstructed flow of blood and thus

blood supply to the heart is achieved. More than 500,000 bypass procedures are performed in the US every year.

However, bypass surgery is a very intrusive procedure requiring expensive and time-consuming surgery. During a bypass operation, an incision is made through the patient's skin and the patient is placed on a bypass pump such that the heart can be operated on, while it is not beating. A saphenous vein graft is harvested from a patient's leg and the vein is then grafted into position between the aorta and the coronary artery to allow unobstructed blood flow. This surgery is both traumatic to the patient and requires a substantial period of time in hospital and prolonged convalescence.

In some circumstances a balloon angioplasty procedure is used instead of the above method, to treat coronary artery plaque occlusion. In this case a deflated balloon catheter is placed within the narrowed segment of the coronary artery. The balloon is then inflated to a high pressure, transmitting circumferential pressure to the plaque occluding the artery, compressing the plaque and thus increasing the diameter through which blood can flow.

Although balloon angioplasty is minimally invasive, this procedure can only be used in a limited number of circumstances.

In addition to the two techniques discussed above, which have been traditionally used to treat coronary artery occlusion, a more recent procedure allows a stent to be positioned between the coronary artery and the left ventricle of the heart such that blood can flow unobstructed from the left ventricle of the heart to the coronary artery, bypassing the occluded portion of the coronary artery. The stent may be positioned between the left ventricle of the heart and the coronary artery using a less invasive procedure than that required for coronary bypass surgery.

Typically the stent is a conduit with a passage extending longitudinally therethrough. Generally a stent is cylindrical in cross section and is generally an elongate tube.

A disadvantage of providing a stent extending from the left ventricle of the heart to the coronary artery is that during diastole blood may reflux from the coronary artery back into the left ventricle of the heart. Such refluxes of blood are undesirable.

Some reports have indicated that backflow of oxygenated blood back into the left ventricle chamber of the heart during diastole can cause the the myocardium to receive an inadequate supply of blood. This can lead to the myocardium becoming ischemic. Indeed, some studies have suggested that measurement of the blood flow during systole and the backflow during diastole indicates that only a 30

percent net flow rate of blood from the left ventricle chamber into the artery is achieved following introduction of a stent between the two compartments.

There remains a need for improved (more efficient) stents.

The present inventor has overcome a number of problems of stents of the prior art.

According to a first aspect of the present invention there is provided a cardiovascular stent comprising a generally tubular body and a synthetic one-way valve capable of moving from a first open position to a second closed position, wherein, in use, movement of fluid, e.g. blood, in a first direction through the stent causes the valve to adopt the open position and movement of fluid in a second opposite direction causes the valve to adopt the closed position.

The valve is deemed to be in the closed position when it restricts the passage of fluid in the second direction e.g. from a second compartment to a first compartment. A stent as described by the present invention can be used to enable the movement of fluid from a proximal position in a first cardiovascular compartment to a distal position in the same cardiovascular compartment or a different cardiovascular compartment.

Preferably in the closed position, the valve allows movement of fluid in the second direction of less than 40% that when the valve is in the open position.

More preferably in the closed position the valve allows movement of fluid in a second direction of less than 30%, preferably less than 20%, even more preferably less than 10%, even more preferably less than 5%, even more preferably less than 2% and most preferably less than 1% that when the valve is in the open position.

A stent with a synthetic valve is advantageous as it can restrict the passage of fluid in a second direction, e.g. from a second compartment to a first compartment, e.g. from a coronary artery to the left ventricle of the heart. This provides for an increase in the net flow rate of blood from the first compartment into the second compartment and minimises the likelihood of e.g. the myocardium, of which the coronary artery provides the blood supply, receiving an inadequate supply of blood.

In such an embodiment the movement of fluid in the first direction e.g. from the first compartment to the second compartment causes a pressure difference across the valve sufficient to cause the valve to adopt the open position. Fluid flow in the second opposite direction, e.g. from the second compartment to the first compartment across the valve, causes the valve to adopt the closed position.

Further, the use of a synthetic valve has the further advantage that a vein does not need to be harvested from the patient.

Preferably in the absence of movement of fluid in either a first or second direction the valve adopts the closed position. Thus preferably the valve is resiliently biased towards the closed configuration.

Preferably the stent is for use in linking cardiovascular compartments.

Preferably the first compartment is a first cardiovascular compartment and the second compartment is a second cardiovascular compartment.

A cardiovascular stent is a stent suitable for use to link one part of a cardiovascular compartment to another part of the same cardiovascular compartment or to another cardiovascular compartment.

A cardiovascular compartment is defined as any organ or any structure of the circulatory system including an artery, vein or chamber of the heart.

In a preferred embodiment the stent is for use as a stent between the left ventricle of the heart and a coronary artery.

Preferably the valve is formed from resilient material.

A valve formed from resilient material is advantageous as it requires few mechanical components to enable the valve to move between the open and closed positions and thus there is less likelihood of damage to red blood corpuscles moved through the stent.

Preferably the flexible resilient material is a suitable biostable biocompatible polymer.

Preferably the flexible resilient material includes Elast-Eon™, Biomer or Biospan.

Details of the polymer Elast-Eon™ can be found in WO98/13405, WO92/00338, WO92/09467, WO99/01496.

In an embodiment in which the valve is formed from resilient material, in the closed position, preferably at least a portion of the aperture formed by the resilient material of the valve is ellipsoidal shape in cross-section. This ellipsoidal shape restricts blood flow from the second cardiovascular compartment into the first cardiovascular compartment.

Preferably the valve is constructed such that movement of fluid such as blood in the first direction through the stent urges the resilient material of the valve to adopt a configuration in which the aperture defined by the material is substantially circular in cross-section thereby

enabling increased fluid to flow through the valve and thus through the stent. Hence, with the circular aperture increased flow from the first cardiovascular compartment into the second cardiovascular compartment is provided.

In an alternative embodiment the valve may comprise at least two leaflets formed from resilient material which when fluid is flowing in the second direction through the stent or when no fluid is flowing through the stent, the leaflets are urged towards each other such that the passage of fluid e.g. blood is minimised. In this embodiment, movement of fluid in the first direction e.g. from a first compartment to a second compartment urges the leaflets of the valve to move apart from each other enabling the passage of fluid through the stent.

The valve may be located at any position in the stent.

Preferably the valve is located at either end of the stent.

Such an embodiment is advantageous as a valve portion of the stent can extend into a cardiovascular compartment. This can be of importance, for example, if the stent is for use between the left ventricle of the heart and the coronary artery as positioning of the valve in the heart muscle may restrict the movement of the valve, as the muscle contracts and relaxes.

Preferably the valve is integral to the stent.

Although a stent may be located and then valve means provided on the stent, it is preferable if the stent and valve are provided in one unit such that they can be located between the cardiovascular compartments in a single procedure.

The stent may be constructed of any suitable material.

The stent may comprise a suitable rigid biocompatible metal which may include, but is not limited to one or more of stainless steel, spring steel, Nitinol and / or a flexible resilient material.

Preferably the stent may be constructed from scaffold mesh.

Preferably the stent comprises a flange portion located towards or at one end of the stent.

This is advantageous as when the stent is pushed into tissue to provide a passage between two compartments the depth of the stent in the tissue can be controlled by the flange portion. If, for example, the flange portion is towards or at the rear portion of the stent, the front portion being the portion inserted first into the tissue, on pushing the stent into tissue from one compartment

to another the flange provided at the rear will prevent the stent being pushed too far into the tissue, ensuring that the lumen of the stent extends from a first compartment into a second compartment. Moreover the flange portion can also be used to secure the stent in position, the tissue at around the flange preventing movement of the stent from a first compartment to a second compartment.

In a preferred embodiment, the valve comprises at least one cantilever member, having a first end and a second end, said cantilever member being pivoted at said first end to the stent, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is open. In a preferred example of such an embodiment when the second end of the cantilever member is in the extended position the material forming the valve and defining the aperture of the valve, when in the open position, is pulled such that the area of the aperture formed by the material is decreased.

In such a preferred example of this embodiment, movement of fluid in a first direction through the stent causes the second end of the cantilever member to resiliently move radially inwards towards the central longitudinal axis of the stent. This movement of the second end of the cantilever member causes the material forming the valve and defining the aperture of the valve to form a larger aperture (preferably substantially circular) in cross section

enabling increased fluid to flow through the valve. As the fluid flow in the first direction is reduced or when there is no fluid flow in the first direction, the cantilever member resiliently pivots to the extended position. This movement of the second end of the cantilever member to the extended position causes the material forming the valve and defining the aperture of the valve to be pulled to form an aperture of reduced area in cross section. As the aperture has less area in cross section than the substantially circular aperture, fluid flow in both the first and second directions is restricted.

More preferably, the valve comprises two cantilever members. In this embodiment the two cantilever members are resiliently pivoted at first ends of the members to the stent. When no fluid is flowing through the stent the second ends of the cantilever members pivot radially outwards to an extended position. Preferably radially greater than the circumference of the stent. When the second ends of the cantilever members are in the extended positions the material forming the valve and defining the aperture of the valve when in the open position is held such that the area of the aperture formed by the material is decreased and forms and ellipsoid in cross section.

Such an embodiment may function as follows: Movement of fluid in a first direction through the stent causes the second ends of the cantilever members to resiliently move radially inwards towards the

central longitudinal axis of the stent. This movement of the second ends of the cantilever members causes the material forming the valve and defining the aperture of the valve to form a substantially circular aperture in cross section enabling blood to flow through the valve.

As the fluid flow in the first direction is reduced, or when there is no fluid flow in the first direction, the second ends of the cantilever members again resiliently pivot to an extended position. The movement of the second ends of the cantilever members to their extended positions again causes the material forming the valve and defining the aperture of the valve to be pulled to form an ellipsoid aperture of reduced area in cross section. As the aperture has less area in cross section than the substantially circular aperture, fluid flow in both the first and second directions is restricted.

With the circular cross section increased flow through the stent is enabled and with the ellipsoidal cross section flow in the second direction is minimised.

In such an embodiment, the aperture formed by the resilient material is preferably pulled from a substantially circular cross section to a substantially ellipsoidal cross section, which, in use, restricts the flow of fluid from a second compartment toward a first compartment.

Preferably the stent is constructed such that it can be expanded in diameter from a "collapsed" configuration to an "expanded" configuration, wherein, in the collapsed configuration, the stent is of narrower diameter that in the expanded configuration.

Such a structure enables the stent to be suitably placed in the body in the narrowed collapsed configuration and then expanded from its collapsed configuration to a fully expanded configuration.

The diameter of the stent can be increased from the collapsed to expanded position using any suitable procedures, for example, using a balloon angioplasty procedure.

In order to position such a stent, the stent, in a collapsed position, may be delivered to the desired location in the body, for example, the heart muscle between the left ventricle and a coronary artery on a catheter. The suitably located stents may then be deployed by expanding a balloon placed in the stent such that the diameter of the stent increases from that of the collapsed stent position to the increased diameter of the stent in the expanded position.

Further to expanding the diameter of the stent by the balloon the stent locks in the expanded position, holding the stent against the heart muscle

and maintaining the stent in its expanded position with increased diameter.

The collapsed stent can be placed by suitable minimally invasive techniques such as percutaneous delivery.

In an alternative embodiment the stent may be constructed of material with memory such that once suitably placed in the body the diameter of the stent expands from a collapsed position to a fully expanded position.

For example, in such an embodiment, the stent may adopt a collapsed position at low temperatures, for example temperatures below body temperature, but an expanded position at body temperature.

In one preferred embodiment, the valve of the stent is moved to a closed position on increasing the diameter of the stent from a collapsed position to an expanded position when the stent is suitably positioned in the body.

In particularly preferred embodiments the valve comprises at least one cantilever member as discussed above. Expansion of diameter of the stent e.g. on deployment of the stent, causes the valve to adopt the closed configuration.

In this embodiment, the cantilever member may be resiliently pivoted at a first end to the stent such

that on expansion of the diameter of the stent a second end of the cantilever member pivots to an extended position in which the material forming the valve and defining the aperture of the valve when in the open position is pulled such that the area of the aperture formed by the material is decreased.

More preferably the valve comprises two cantilever members which, on deployment of the stent, cause the diameter of the stent to expand from a collapsed configuration in which the valve portion of the stent is in an open position to an expanded configuration in which the valve is in a closed position. With the circular cross section increased flow through the stent is enabled and with the ellipsoidal cross section flow in the second direction is minimised.

In such an embodiment, the aperture formed by the resilient material is preferably pulled from a substantially circular cross section to a substantially ellipsoidal cross section, which, in use, restricts the flow of fluid from a second compartment toward a first compartment.

The diameter and length of the stent depends on its use. For example, the stent may be of suitable length to extend between the left ventricle of heart and coronary artery.

Preferably the stent is two to fifteen millimetres in diameter.

The stent may be constructed such that a number of stents may be positioned "end to end" to increase the effective length of the stent arrangment.

Thus, in one preferred embodiment the stent is resiliently deformable at at least one end to receive and enable connection with a second stent.

In an alternative embodiment the stent may be shaped at one or both ends to enable connection to a second stent.

The stent may comprise drug coatings or chemical and / or mechanical coatings such as a TEFLON ™ membrane to minimise stenosis.

As described above, stents of the present invention may be used to link or repair two cardiovascular compartments.

For example, stents of the invention may be used to link a coronary artery to the left ventricle of the heart.

Stents of the present invention may also be used in non coronary structures e.g. non coronary veins and / or arteries.

For example, the stents may be used to link a first portion of an ascending venous structure such as the saphenous vein and a second portion of the same

ascending venous structure. If the region between the first and second portions of the femoral artery is damaged or occluded, a stent of the invention may be located between the first and second portions to enable the movement of blood from the first portion to the second portion.

Thus in use, a stent of the present invention may be provided between a first and second portion of a vein e.g. a saphenous vein, to allow blood to flow from the first portion to the second portion, but restrict blood flow from the second portion to the first portion. Such an arrangement could be used to treat varicose veins.

In a second aspect of the present invention there is provided a method for treating a full or partial occlusion of a blood vessel comprising the step of

providing stent means wherein said stent means comprise at least one stent of the first aspect of the invention,

a first end of the lumen of the stent means being in communication with a cardiovascular compartment on one side of the occlusion,

the second end of the lumen of the stent means being in communication with a cardiovascular compartment on the other side of the occlusion allowing blood flow from the first side to the

second side of the cardiovascular compartment through the lumen of the stent means.

The cardiovascular compartments on each side of the occlusion may be in same the blood vessel in which the occlusion is present.

In alternative embodiments the cardiovascular compartments may be different compartments, for example the left ventricle of the heart and a coronary artery.

The stent means may comprise a single stent. Alternatively the stent means may comprise a plurality of stents longitudinally aligned to allow the flow of blood from a stent at a first end of the stent means to a stent at a second end of the stent means.

Preferably the stent means comprise a single stent of the first aspect of the invention.

In preferred embodiments the method further comprises the step of positioning the stent means between the compartments, increasing the diameter of the stent means from a reduced diameter in a collapsed position to an increased diameter in an expanded position.

In particularly preferred embodiments the method comprises the steps of

inserting the stent into position between a first cardiovascular compartment and a second cardiovascular compartment;

expanding the diameter of the stent such that the valve is moved to the closed position, but can move to the open position when fluid flows in a first direction from a first cardiovascular compartment to a second cardiovascular compartment.

According to a further aspect of the invention there is provided a method for treating varicose veins comprising positioning stent means comprising at least one stent of the first aspect of the invention in a vein or replacing all or part of a vein with stent means comprising at least one stent of the first aspect of the invention.

As above, stent means may comprise a plurality of stents longitudinally aligned to allow the flow of fluid from a stent at a first end of the stent means to a stent at a second end of the stent means.

As described above, in a preferred embodiment of a first aspect of the invention a stent comprising a valve comprising at least one cantilever member is provided. The use of such a valve is not limited to uses within the body. Accordingly, in a further independent aspect there is provided tube means, said tube means comprising a valve which comprises at least one cantilever member, having a first end

and a second end, said cantilever member being pivoted at said first end to the tube, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is open.

Tubes comprising such valves may be used to link a first cardiovascular compartment with a compartment in a cardiovascular device or *vice versa*.

In a further embodiment tubes comprising such valves may be used to link first and second compartments in a device to transport fluid, for example blood.

For example, such tubes comprising at least one cantilever member can be used in machines or devices used to move fluid, for example blood, such as dialysis machines.

A further independent aspect of the present invention is a device for the movement of fluid.

Preferably the fluid is blood.

The present invention will now be described, by way of example only, with reference to the accompanying figures in which;

Figure 1 is an illustration of an embodiment of a stent of the present invention extending from

the left ventricle of the heart into the coronary artery;

Figure 2 is an enlarged view of an embodiment of a stent of the present invention connecting the left ventricle of the heart to the coronary artery;

Figure 3 is an illustration of an embodiment of a stent of the present invention wherein a second end of the stent is in a closed position;

Figure 4 (A) is an illustration of an embodiment of a stent in a collapsed form, (B) is an illustration of an embodiment of a stent of the present invention in an expanded form;

Figure 5 is an illustration of an embodiment of a stent of the present invention where a second end of a stent is in an open position;

Figure 6 is an illustration of at least two embodiments of stents of the present invention aligned along their longitudinal axes such that blood can flow from the lumen of a first stent to the lumen of a second adjacent stent; and

Figure 7 is an illustration of stents according to an embodiment of the present invention aligned along their longitudinal length wherein the first stent has a shaped end to receive the

second stent and another stent is deformable to receive a stent inside one end.

As shown in figure 1, the coronary artery 10 is known to branch off the aorta 12 and be positioned along the external surface of the heart wall 14.

Following oxygenation of the blood, the oxygenated blood flows from the heart 16 into the aorta 12 and onto the rest of the body. Some of the oxygenated blood is circulated along the coronary artery 10 in order to oxygenate the muscles of the heart. In some individuals an occlusion is formed within the coronary artery due to plaque build up. These occlusions can lead to a variety of symptoms and diseases ranging from mild angina to heart attack.

In order to allow blood flow around the occlusion within the coronary artery and to at least partially restore the flow of oxygenated blood through the coronary artery, it is possible to bypass the blocked portion of the coronary artery by providing a stent 18 which extends from the left ventricle 20 of the heart into the coronary artery 10, as shown in figure 2. Location of the stent 18 as shown in figure 2 allows blood to flow unobstructed from the left ventricle 20 of the heart to the coronary artery 10.

Allowing blood flow past or around occlusions of the coronary artery 10 using a stent 18 is preferable to traditional bypass surgery in that the stent 18 may

be located and fitted using minimally invasive techniques. Generally the stents previously used to connect the left ventricle 20 of the heart to the coronary artery 10 are stents formed by hollow tubes comprising biocompatible material such as titanium alloys, nickel alloys or biocompatible polymers. These tubes may be provided and located between the left ventricle 20 of the heart and the coronary artery 10 in a collapsed position and when suitably located, expanded from a collapsed position to a fully expanded position, using an inflatable balloon catheter or other method.

Although such stents allow the flow of blood from the left ventricle 20 of the heart into the coronary artery, no artificial or mechanical means are present on conventional stents to restrict the backflow of blood.

As shown in figure 3, a stent of the present invention is provided with a synthetic valve 22, one example of the valve being a portion of flexible resilient material located at the second end 24 of the stent. This flexible resilient material is preferably integral with the rest of the stent.

The valve may be formed during manufacture of the stent, prior to insertion of the stent into the body.

Alternatively, as shown in the embodiment of the stent in figure 4, the valve can be created by the

pivotal movement of cantilever members during the movement of the stent from a collapsed position to an expanded position, while the stent is located in the body.

As shown in figure 4a, in this embodiment, in a collapsed position, the resilient material, held by two cantilever members 21, forms a substantially cylindrical aperture 28.

The cantilever members are conjoined to the stent at a first end only and from the rigid biocompatible metal portion 23 of the stent. On deployment (expansion of diameter) of the stent, the second ends of the cantilevers move away from each other to an extended position. This movement pulls the resilient material such that its cross sectional shape is changed from substantially circular to substantially ellipsoidal. The change in the cross sectional shape restricts the flow of blood in a second direction from the second compartment into the first compartment through the stent. Blood flow through the stent from a first compartment to a second compartment causes the material of the leaflets to be pushed such that the cantilever members resiliently move towards each other and the aperture of the valve becomes substantially circular in cross section. The area of the circular cross section is larger that the ellipsoidal cross section and blood can thus easily flow from the first compartment to the second compartment. During diastole, when blood is not being pushed from the

first compartment to the second compartment, the pressure of the blood on the material of the valve decreases. The second ends of the resilient cantilever members can again move away from each other and cause the valve material to form an ellipsoidal cross section.

It can be appreciated that if more than two cantilevers are used for example, three, four or five cantilevers, then on deployment, the cross sectional shape will not be elliptical, but substantially triangular, rectangular or pentacle shaped. Different shaped openings may be used as appropriate to restrict the flow of blood from the second compartment to the first compartment. In addition, different shaped openings can be chosen to minimise pressure on the arterial wall caused by the cantilever members.

In one embodiment, a valve formed from resilient material does not require expansion of the diameter of the stent to cause the resilient material to adopt the closed position. In this embodiment cantilever members are not required to pull the material of the valve to a closed position and the valve is manufactured in the closed position. Blood flow in a first direction from the first compartment towards the second compartment causes the resilient material to adopt an open position.

In addition to the cantilever members disclosed herein, different methods of urging the resilient

material to a closed position following expansion of a stent structure from a collapsed position can be envisaged.

During systole (contraction of the heart) the blood is pumped by the heart through the stent 18 from the first end 26 located at the left ventricle 20 of the heart towards the second end 24 of the stent located at the coronary artery. On contraction of the heart, the blood of the left ventricle of the heart is moved in a first direction through the stent causing the valve to move from an ellipsoidal shape (closed position) to an open (circular cross sectional shape) position.

In the closed position the ellipsoidal shape causes the area through which blood can flow from the second compartment to the first compartment to be reduced to 10% the area of the open position of the valve. The backflow of blood is thus reduced when blood is not being pumped through the stent from the first compartment to the second compartment.

Typically reflux of blood through the valve from the second compartment to the first compartment may be 25% that which would be expected if the valve is in the open position.

The movement of the resilient material in this manner, from an ellipsoidal shape (closed position) towards a circular shape (open position), increases the area of the aperture 28 through which the blood

can flow from the first compartment (in this case the left ventricle of the heart) into the second compartment (in this case the coronary artery) and allows the unobstructed flow of blood through the valve.

As the pressure of the blood flow through the valve in a first direction decreases, the resilient material is urged by the material (and in particular embodiments the cantilever members of the rigid portion of the stent) to cause the valve to adopt a resting position, wherein the aperture of the valve into the coronary artery forms an ellipsoidal shape. This change in shape of the aperture reduces the area of the aperture located at the second compartment and minimises the blood flow from the coronary artery into the left ventricle of the heart.

Movement of the stent from a collapsed position to an expanded position causes the stent to be gripped by the heart muscle. A flange or other projection may also be provided on the stent to aid location of the stent.

As shown in figures 6 and 7 at least two stents can be aligned along their longitudinal axes such that blood can be communicated from the lumen of a first stent to the lumen of a second adjacent stent. By aligning several stents together, blood may be moved from a first proximal position to a second distal position, either between two different

cardiovascular compartments such as the left ventricle of the heart and a coronary artery or within the same cardiovascular compartments such as a blood vessel.

By aligning a number of stents along their longitudinal axis it is possible to allow blood flow to be effected over a relatively large distance. In addition, as each of the stents comprise a valve, the stents more closely mimic the situation in actual veins preventing the backflow of blood and allowing blood to be moved upwards. An example of when the blood may be required to be moved upwards is in the leg of a patient when said patient is standing.

The valves present on each of the stents allow blood to be pushed through the valve on contraction of the heart, but minimise the backward movement of the blood during diastole. This allows blood to be moved up the leg and through the body.

To allow the stents to be conjoined to each other, a first end of a stent may be capable of deformation (as shown in figure 7 (30)) to allow a second stent to be partially inserted therein. Alternatively or additionally the stent may also be widened (figure 7 (32)) to allow ingress of a second stent as shown in figure 7.

It can be appreciated that various improvements and modifications can be made without departing from the

scope of the present invention. In particular it can be envisaged that the valve may be formed from at least two leaflets, which in a resting position are urged towards each other minimising blood flow from the second cardiovascular compartment into the first cardiovascular compartment. On movement of blood in a first direction through the stent, from the first compartment to the second compartment, these leaflets may be pushed apart from each other, enabling blood flow from the first compartment into the second compartment. During diastole the two leaflets of the valve will be urged towards each other due to the resilience of the material. Alternatively, different methods may be used to align the stents along their longitudinal length such as providing junction means.

Claims

1. A cardiovascular stent comprising:
a generally tubular body, and
a synthetic one-way valve capable of moving from a first open position to a second closed position, wherein, in use, movement of fluid in a first direction through the stent causes the valve to adopt the open position and movement of fluid in a second opposite direction causes the valve to adopt the closed position.

2. A cardiovascular stent as claimed in claim 1 wherein the valve is formed from resilient material.

3. A cardiovascular stent as claimed in claim 2 wherein the valve is constructed such that, in use, movement of fluid in the first direction through the stent urges the resilient material of the valve to adopt a configuration in which the aperture defined by the material is substantially circular in cross-section thereby enabling increased fluid to flow through the valve and thus through the stent.

4. A cardiovascular stent as claimed in claim 2 or 3 wherein the valve comprises two leaflets formed from resilient material and wherein, in use, when fluid is flowing in the second direction through the stent or when no fluid is flowing through the stent, the leaflets are

urged towards each other such that the passage of fluid is minimised.

5. A cardiovascular stent as claimed in any one of the preceding claims, wherein the valve comprises at least one cantilever member having a first end and a second end, said cantilever member being pivoted at said first end to the stent, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is in the open position.

6. A cardiovascular stent as claimed in claim 5 wherein the valve comprises two cantilever members.

7. A cardiovascular stent as claimed in any one of the preceding claims wherein the stent is constructed such that it can be expanded in diameter from a "collapsed" configuration to an "expanded" configuration, wherein in the collapsed configuration, the stent is of narrower diameter than in the expanded configuration.

8. A cardiovascular stent as claimed in claim 7 when dependent on claim 5 or claim 6 wherein on expansion of the diameter of the stent, the second end of the cantilever member pivots to an extended position in which the material

forming the valve and defining the aperture of the valve when in the open position is pulled such that the area of the aperture formed by the material is decreased.

9. A cardiovascular stent as claimed in any one of the preceding claims wherein the stent is resiliently deformable at one or both ends to receive and enable connection with a second stent.

10. A cardiovascular stent as claimed in any of one of the preceding claims wherein the stent is shaped at one or both ends to enable connection to a second stent.

11. A cardiovascular stent as claimed in any one of the preceding claims for linking a coronary artery to the left ventricle of the heart.

12. A cardiovascular stent as claimed in any one of claims 1 to 10 for linking a first portion of an ascending venous structure and a second portion of the same ascending venous structure.

13. A method for treating a full or partial occlusion of a blood vessel comprising the steps of:

providing stent means wherein said stent means comprise at least one stent as claimed in claims 1 to 12, a first end of the lumen of the

stent means being in communication with a cardiovascular compartment on a first side of the occlusion,

the second end of the lumen of the stent means being in communication with a cardiovascular compartment on the other side of the occlusion and allowing blood flow from the first side of the occlusion to the other side of the cardiovascular compartment through the lumen of the stent means.

14. A method as claimed in claim 13 wherein the stent means comprises a plurality of stents longitudinally aligned to allow the flow of blood from a stent at a first end of the stent means to a stent at a second end of the stent means.

15. A method as claimed in claim 13 or claim 14 further comprising the step of increasing the diameter of the stent from a reduced diameter in a collapsed position to an increased diameter in an expanded position.

16. A method for treating varicose veins comprising the step of:

positioning stent means comprising at least one stent as claimed in claims 1 to 12 in a vein.

17. A method for treating varicose veins comprising the step of:

replacing at least a part of a vein with stent means comprising at least one stent of the first aspect of the invention.

18. Tube means comprising a tubular portion and a valve, said valve comprising at least one cantilever member having a first end and a second end, said cantilever member being pivoted at said first end to the tubular portion, the cantilever member being resiliently pivotable from a first extended position in which the valve is in the closed position to a second position in which the valve is in the open position.

19. Tube means as claimed in claim 18 wherein in moving from the closed position to the open position the aperture of the valve is moved from being ellipisoidal to substantially circular.

20. A device for moving fluid comprising a tube as claimed in claims 18 or 19.

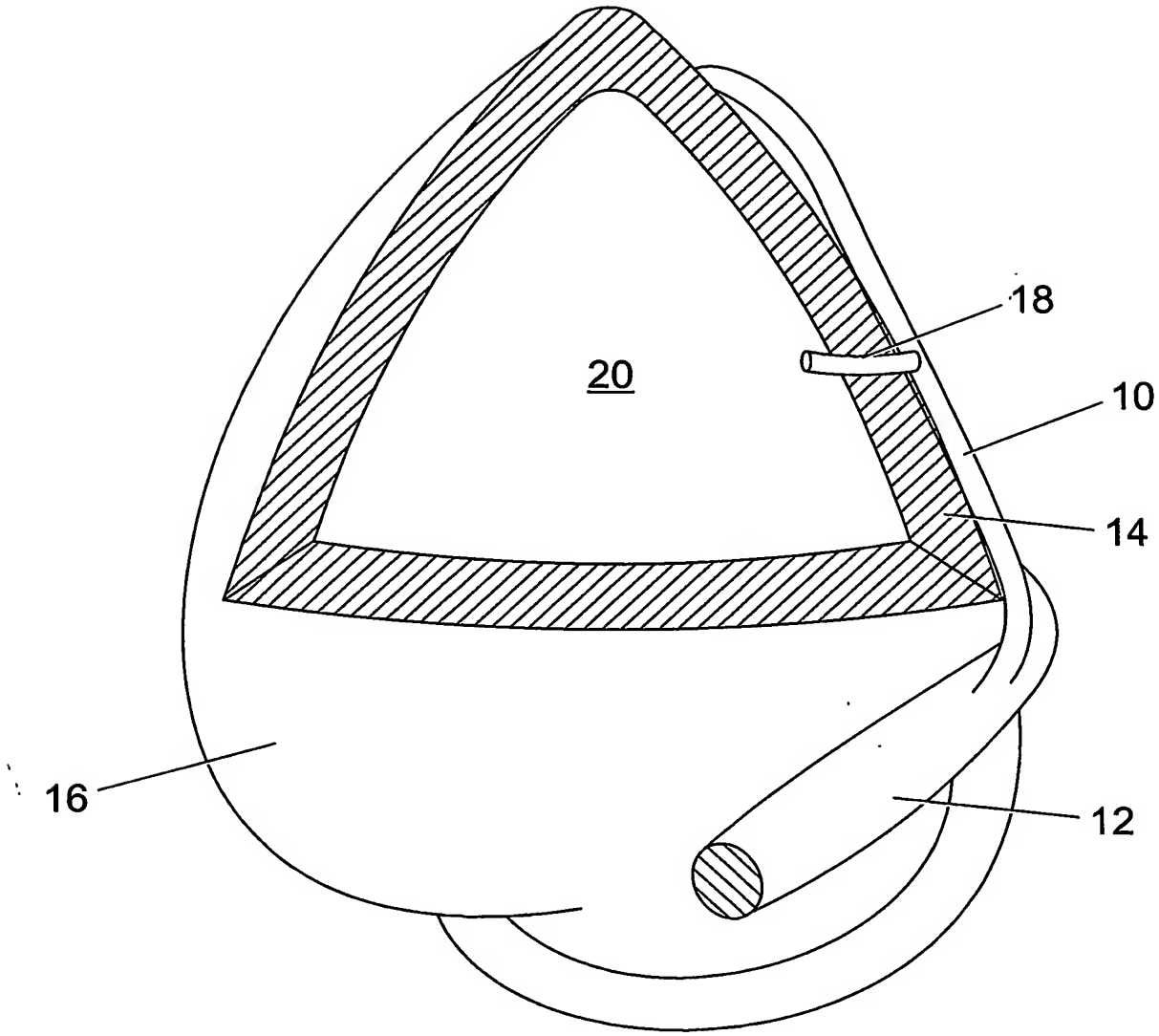


Fig. 1

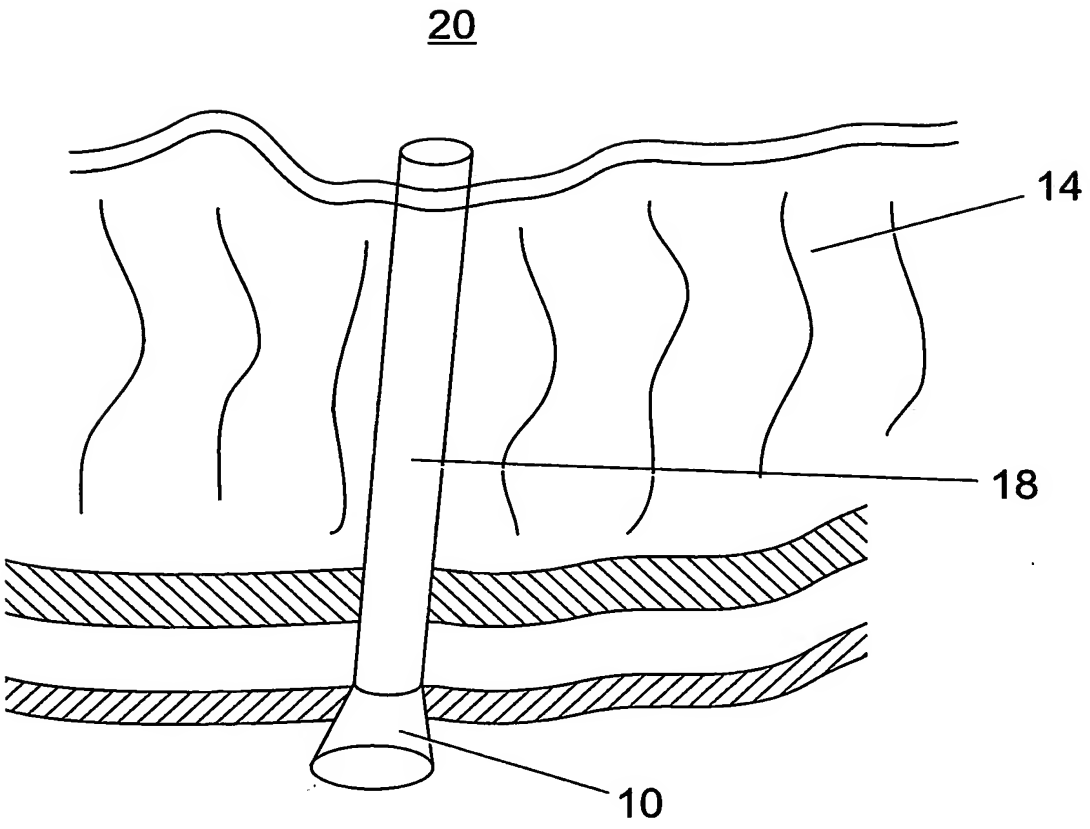


Fig. 2

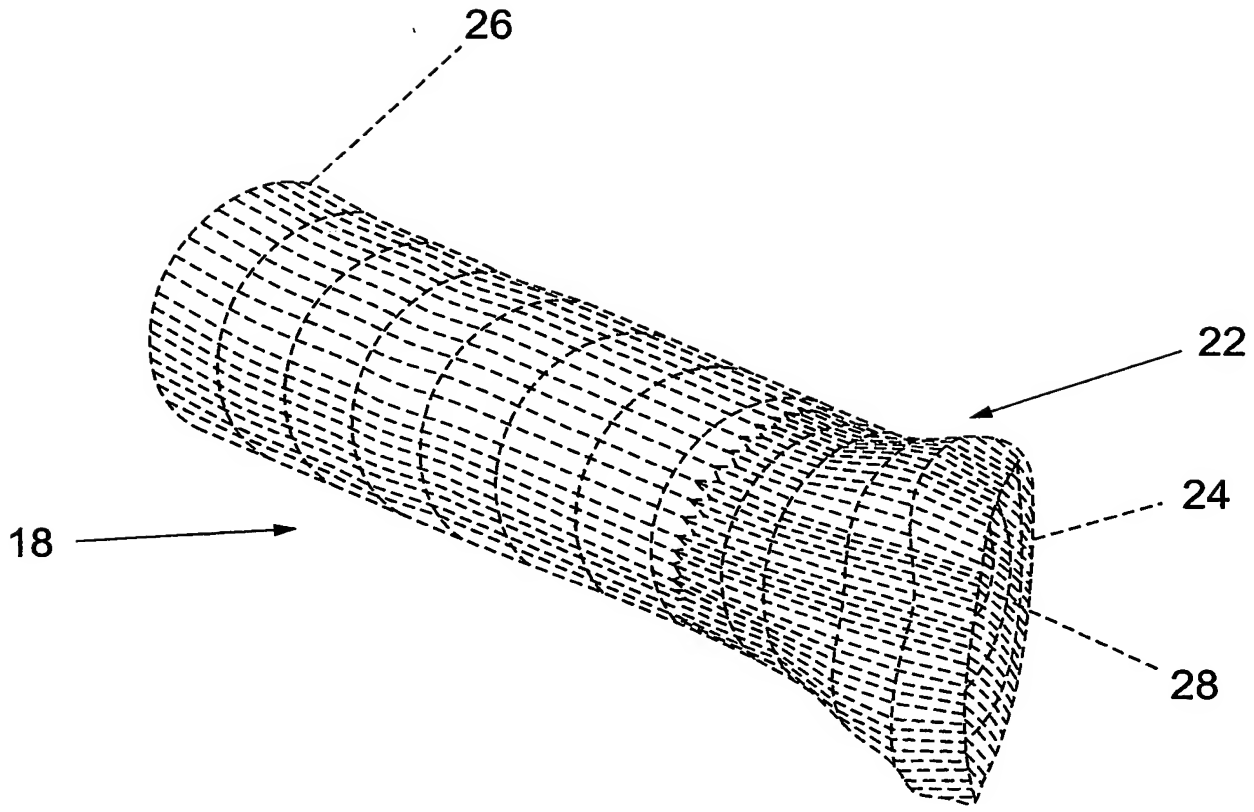


Fig. 3

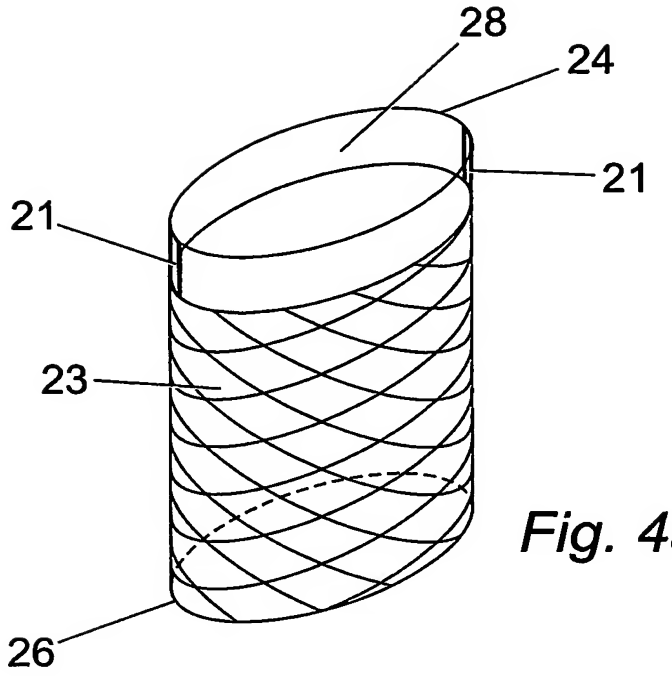


Fig. 4a

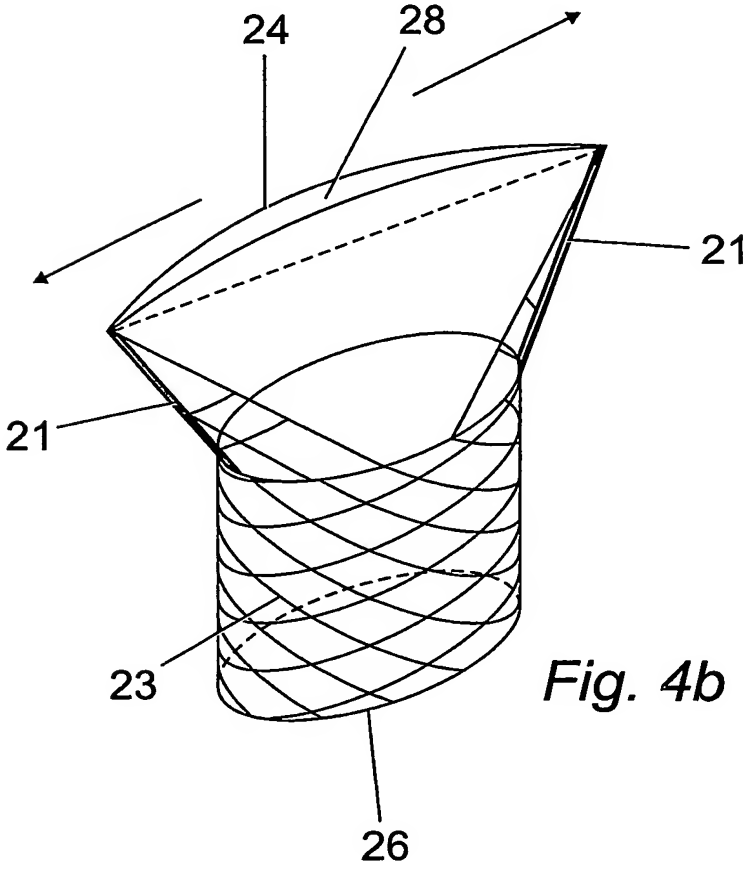


Fig. 4b

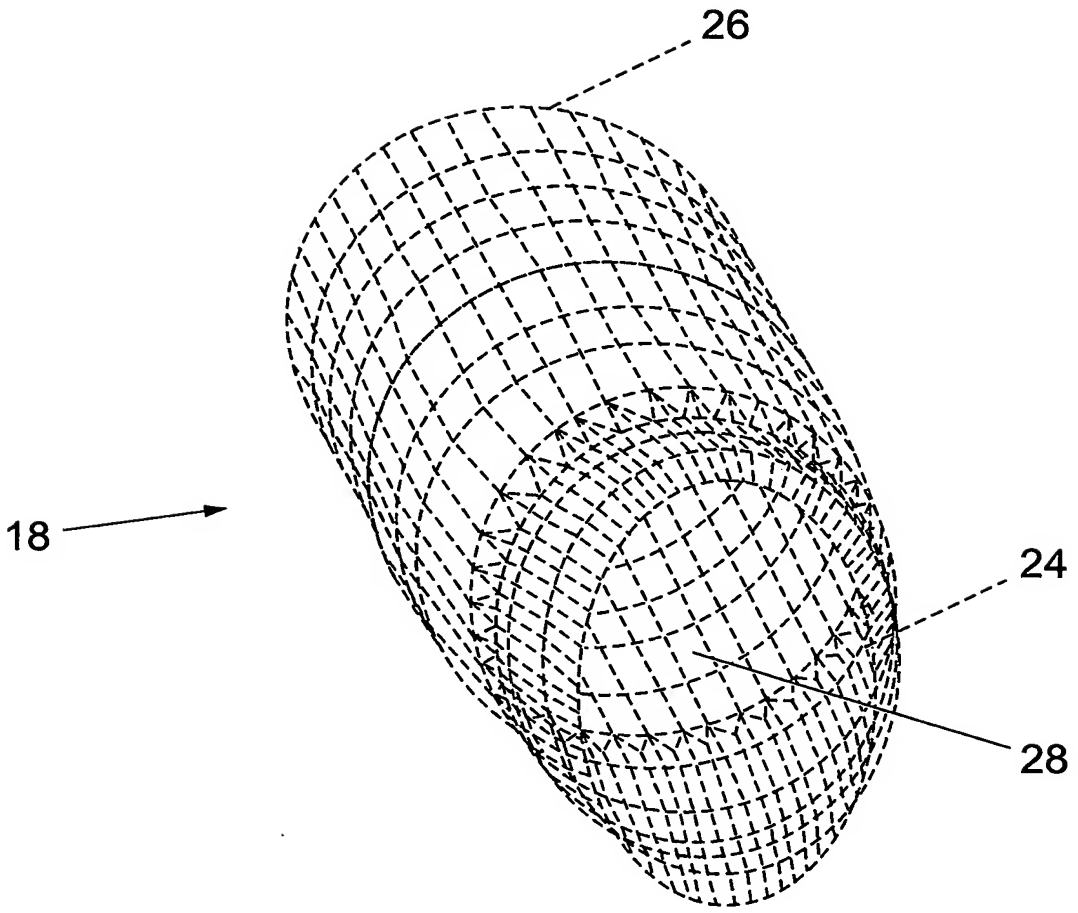


Fig. 5

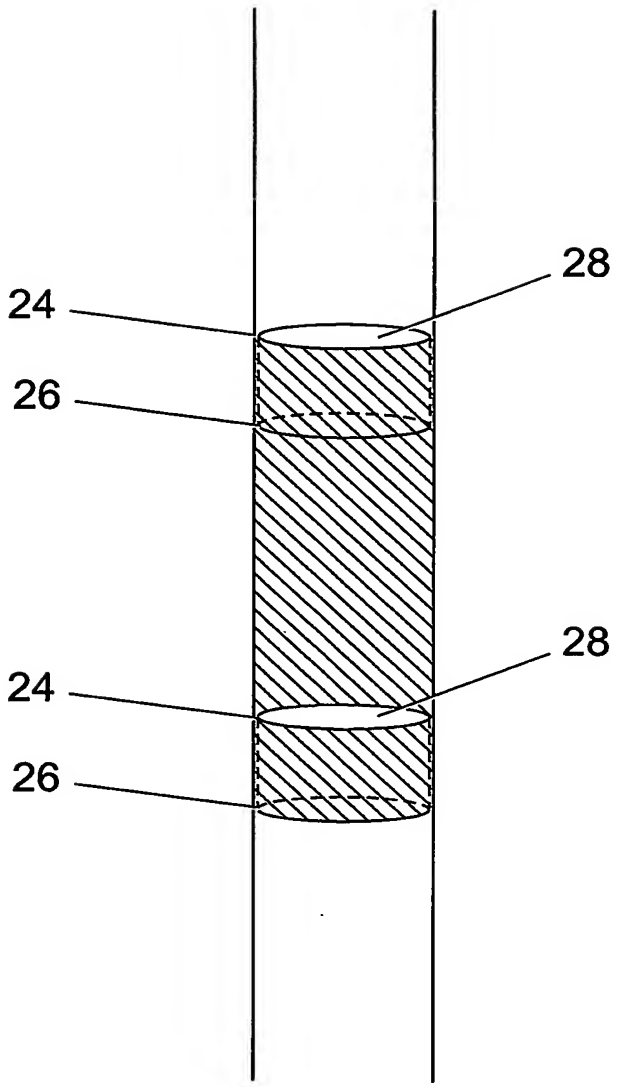


Fig. 6

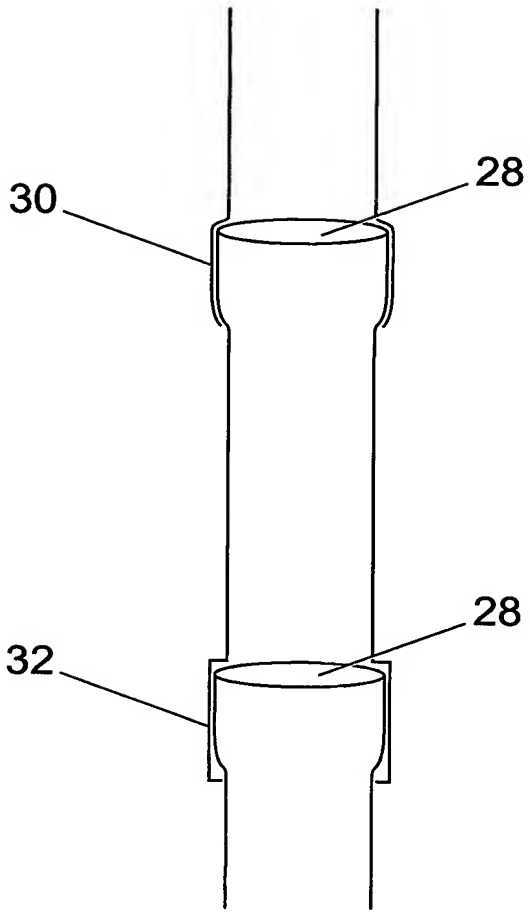


Fig. 7

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(71) Applicant *(for all designated States except US)*: **AORTECH INTERNATIONAL PLC** [GB/GB]; Phoenix Crescent Business Park, Bellshill ML4 3NJ (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **BEITH, Jason** [GB/US]; Edwards Lifescience, On edwards Way, Irvine, CA 92614 (US).

(74) Agent: **MURGITROYD & COMPANY**; Scotland House, 165-169 Scotland Street, Glasgow G5 8PL (GB).

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(54) Title: BLOOD REGULATION DEVICE

(57) Abstract: The present invention relates to a cardiovascular stent (18) including a generally tubular body and a synthetic valve (22) capable of moving from a first open position to a second closed position wherein, in use, the stent is located between a first compartment and a second compartment and movement of blood in one direction causes the valve to move to an open position and movement of blood in a second opposite direction causes the valve to move to a closed position. In particular a stent is provided to connect the left ventricle of the heart to a coronary artery which allows blood to flow through the stent from the left ventricle of the heart into a coronary artery, but minimises reflux of blood from the coronary artery to the left ventricle of the heart.

WO 2004/019814 A2

"Blood Regulation Device"

The present invention relates to stents for connecting a first compartment to a second compartment. In particular, the invention relates to cardiovascular stents e.g. for connection of the left ventricle of the heart to a coronary artery.

Coronary artery disease is a major problem thoughout the world, particularly in Western society. Coronary arteries, as well as other blood vessels, can become clogged with plaque, impairing the efficiency of the heart's pumping action. This can lead to heart attacks, angina and death.

A number of methods are used to treat clogged coronary arteries such as bypass operations or balloon angioplasty.

In bypass operations one or more venous segments are inserted between the aorta and the coronary arteries to bypass the blocked portion of the coronary artery such that an unobstructed flow of blood and thus

blood supply to the heart is achieved. More than 500,000 bypass procedures are performed in the US every year.

However, bypass surgery is a very intrusive procedure requiring expensive and time-consuming surgery. During a bypass operation, an incision is made through the patient's skin and the patient is placed on a bypass pump such that the heart can be operated on, while it is not beating. A saphenous vein graft is harvested from a patient's leg and the vein is then grafted into position between the aorta and the coronary artery to allow unobstructed blood flow. This surgery is both traumatic to the patient and requires a substantial period of time in hospital and prolonged convalescence.

In some circumstances a balloon angioplasty procedure is used instead of the above method, to treat coronary artery plaque occlusion. In this case a deflated balloon catheter is placed within the narrowed segment of the coronary artery. The balloon is then inflated to a high pressure, transmitting circumferential pressure to the plaque occluding the artery, compressing the plaque and thus increasing the diameter through which blood can flow.

Although balloon angioplasty is minimally invasive, this procedure can only be used in a limited number of circumstances.

In addition to the two techniques discussed above, which have been traditionally used to treat coronary artery occlusion, a more recent procedure allows a stent to be positioned between the coronary artery and the left ventricle of the heart such that blood can flow unobstructed from the left ventricle of the heart to the coronary artery, bypassing the occluded portion of the coronary artery. The stent may be positioned between the left ventricle of the heart and the coronary artery using a less invasive procedure than that required for coronary bypass surgery.

Typically the stent is a conduit with a passage extending longitudinally therethrough. Generally a stent is cylindrical in cross section and is generally an elongate tube.

A disadvantage of providing a stent extending from the left ventricle of the heart to the coronary artery is that during diastole blood may reflux from the coronary artery back into the left ventricle of the heart. Such refluxes of blood are undesirable.

Some reports have indicated that backflow of oxygenated blood back into the left ventricle chamber of the heart during diastole can cause the the myocardium to receive an inadequate supply of blood. This can lead to the myocardium becoming ischemic. Indeed, some studies have suggested that measurement of the blood flow during systole and the backflow during diastole indicates that only a 30

percent net flow rate of blood from the left ventricle chamber into the artery is achieved following introduction of a stent between the two compartments.

There remains a need for improved (more efficient) stents.

The present inventor has overcome a number of problems of stents of the prior art.

According to a first aspect of the present invention there is provided a cardiovascular stent comprising a generally tubular body and a synthetic one-way valve capable of moving from a first open position to a second closed position, wherein, in use, movement of fluid, e.g. blood, in a first direction through the stent causes the valve to adopt the open position and movement of fluid in a second opposite direction causes the valve to adopt the closed position.

The valve is deemed to be in the closed position when it restricts the passage of fluid in the second direction e.g. from a second compartment to a first compartment. A stent as described by the present invention can be used to enable the movement of fluid from a proximal position in a first cardiovascular compartment to a distal position in the same cardiovascular compartment or a different cardiovascular compartment.

Preferably in the closed position, the valve allows movement of fluid in the second direction of less than 40% that when the valve is in the open position.

More preferably in the closed position the valve allows movement of fluid in a second direction of less than 30%, preferably less than 20%, even more preferably less than 10%, even more preferably less than 5%, even more preferably less than 2% and most preferably less than 1% that when the valve is in the open position.

A stent with a synthetic valve is advantageous as it can restrict the passage of fluid in a second direction, e.g. from a second compartment to a first compartment, e.g. from a coronary artery to the left ventricle of the heart. This provides for an increase in the net flow rate of blood from the first compartment into the second compartment and minimises the likelihood of e.g. the myocardium, of which the coronary artery provides the blood supply, receiving an inadequate supply of blood.

In such an embodiment the movement of fluid in the first direction e.g. from the first compartment to the second compartment causes a pressure difference across the valve sufficient to cause the valve to adopt the open position. Fluid flow in the second opposite direction, e.g. from the second compartment to the first compartment across the valve, causes the valve to adopt the closed position.

Further, the use of a synthetic valve has the further advantage that a vein does not need to be harvested from the patient.

Preferably in the absence of movement of fluid in either a first or second direction the valve adopts the closed position. Thus preferably the valve is resiliently biased towards the closed configuration.

Preferably the stent is for use in linking cardiovascular compartments.

Preferably the first compartment is a first cardiovascular compartment and the second compartment is a second cardiovascular compartment.

A cardiovascular stent is a stent suitable for use to link one part of a cardiovascular compartment to another part of the same cardiovascular compartment or to another cardiovascular compartment.

A cardiovascular compartment is defined as any organ or any structure of the circulatory system including an artery, vein or chamber of the heart.

In a preferred embodiment the stent is for use as a stent between the left ventricle of the heart and a coronary artery.

Preferably the valve is formed from resilient material.

A valve formed from resilient material is advantageous as it requires few mechanical components to enable the valve to move between the open and closed positions and thus there is less likelihood of damage to red blood corpuscles moved through the stent.

Preferably the flexible resilient material is a suitable biostable biocompatible polymer.

Preferably the flexible resilient material includes Elast-Eon™, Biomer or Biospan.

Details of the polymer Elast-Eon™ can be found in WO98/13405, WO92/00338, WO92/09467, WO99/01496.

In an embodiment in which the valve is formed from resilient material, in the closed position, preferably at least a portion of the aperture formed by the resilient material of the valve is ellipsoidal shape in cross-section. This ellipsoidal shape restricts blood flow from the second cardiovascular compartment into the first cardiovascular compartment.

Preferably the valve is constructed such that movement of fluid such as blood in the first direction through the stent urges the resilient material of the valve to adopt a configuration in which the aperture defined by the material is substantially circular in cross-section thereby

enabling increased fluid to flow through the valve and thus through the stent. Hence, with the circular aperture increased flow from the first cardiovascular compartment into the second cardiovascular compartment is provided.

In an alternative embodiment the valve may comprise at least two leaflets formed from resilient material which when fluid is flowing in the second direction through the stent or when no fluid is flowing through the stent, the leaflets are urged towards each other such that the passage of fluid e.g. blood is minimised. In this embodiment, movement of fluid in the first direction e.g. from a first compartment to a second compartment urges the leaflets of the valve to move apart from each other enabling the passage of fluid through the stent.

The valve may be located at any position in the stent.

Preferably the valve is located at either end of the stent.

Such an embodiment is advantageous as a valve portion of the stent can extend into a cardiovascular compartment. This can be of importance, for example, if the stent is for use between the left ventricle of the heart and the coronary artery as positioning of the valve in the heart muscle may restrict the movement of the valve, as the muscle contracts and relaxes.

Preferably the valve is integral to the stent.

Although a stent may be located and then valve means provided on the stent, it is preferable if the stent and valve are provided in one unit such that they can be located between the cardiovascular compartments in a single procedure.

The stent may be constructed of any suitable material.

The stent may comprise a suitable rigid biocompatible metal which may include, but is not limited to one or more of stainless steel, spring steel, Nitinol and / or a flexible resilient material.

Preferably the stent may be constructed from scaffold mesh.

Preferably the stent comprises a flange portion located towards or at one end of the stent.

This is advantageous as when the stent is pushed into tissue to provide a passage between two compartments the depth of the stent in the tissue can be controlled by the flange portion. If, for example, the flange portion is towards or at the rear portion of the stent, the front portion being the portion inserted first into the tissue, on pushing the stent into tissue from one compartment

to another the flange provided at the rear will prevent the stent being pushed too far into the tissue, ensuring that the lumen of the stent extends from a first compartment into a second compartment. Moreover the flange portion can also be used to secure the stent in position, the tissue at around the flange preventing movement of the stent from a first compartment to a second compartment.

In a preferred embodiment, the valve comprises at least one cantilever member, having a first end and a second end, said cantilever member being pivoted at said first end to the stent, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is open. In a preferred example of such an embodiment when the second end of the cantilever member is in the extended position the material forming the valve and defining the aperture of the valve, when in the open position, is pulled such that the area of the aperture formed by the material is decreased.

In such a preferred example of this embodiment, movement of fluid in a first direction through the stent causes the second end of the cantilever member to resiliently move radially inwards towards the central longitudinal axis of the stent. This movement of the second end of the cantilever member causes the material forming the valve and defining the aperture of the valve to form a larger aperture (preferably substantially circular) in cross section

enabling increased fluid to flow through the valve. As the fluid flow in the first direction is reduced or when there is no fluid flow in the first direction, the cantilever member resiliently pivots to the extended position. This movement of the second end of the cantilever member to the extended position causes the material forming the valve and defining the aperture of the valve to be pulled to form an aperture of reduced area in cross section. As the aperture has less area in cross section than the substantially circular aperture, fluid flow in both the first and second directions is restricted.

More preferably, the valve comprises two cantilever members. In this embodiment the two cantilever members are resiliently pivoted at first ends of the members to the stent. When no fluid is flowing through the stent the second ends of the cantilever members pivot radially outwards to an extended position. Preferably radially greater than the circumference of the stent. When the second ends of the cantilever members are in the extended positions the material forming the valve and defining the aperture of the valve when in the open position is held such that the area of the aperture formed by the material is decreased and forms and ellipsoid in cross section.

Such an embodiment may function as follows: Movement of fluid in a first direction through the stent causes the second ends of the cantilever members to resiliently move radially inwards towards the

central longitudinal axis of the stent. This movement of the second ends of the cantilever members causes the material forming the valve and defining the aperture of the valve to form a substantially circular aperture in cross section enabling blood to flow through the valve.

As the fluid flow in the first direction is reduced, or when there is no fluid flow in the first direction, the second ends of the cantilever members again resiliently pivot to an extended position. The movement of the second ends of the cantilever members to their extended positions again causes the material forming the valve and defining the aperture of the valve to be pulled to form an ellipsoid aperture of reduced area in cross section. As the aperture has less area in cross section than the substantially circular aperture, fluid flow in both the first and second directions is restricted.

With the circular cross section increased flow through the stent is enabled and with the ellipsoidal cross section flow in the second direction is minimised.

In such an embodiment, the aperture formed by the resilient material is preferably pulled from a substantially circular cross section to a substantially ellipsoidal cross section, which, in use, restricts the flow of fluid from a second compartment toward a first compartment.

Preferably the stent is constructed such that it can be expanded in diameter from a "collapsed" configuration to an "expanded" configuration, wherein, in the collapsed configuration, the stent is of narrower diameter that in the expanded configuration.

Such a structure enables the stent to be suitably placed in the body in the narrowed collapsed configuration and then expanded from its collapsed configuration to a fully expanded configuration.

The diameter of the stent can be increased from the collapsed to expanded position using any suitable procedures, for example, using a balloon angioplasty procedure.

In order to position such a stent, the stent, in a collapsed position, may be delivered to the desired location in the body, for example, the heart muscle between the left ventricle and a coronary artery on a catheter. The suitably located stents may then be deployed by expanding a balloon placed in the stent such that the diameter of the stent increases from that of the collapsed stent position to the increased diameter of the stent in the expanded position.

Further to expanding the diameter of the stent by the balloon the stent locks in the expanded position, holding the stent against the heart muscle

and maintaining the stent in its expanded position with increased diameter.

The collapsed stent can be placed by suitable minimally invasive techniques such as percutaneous delivery.

In an alternative embodiment the stent may be constructed of material with memory such that once suitably placed in the body the diameter of the stent expands from a collapsed position to a fully expanded position.

For example, in such an embodiment, the stent may adopt a collapsed position at low temperatures, for example temperatures below body temperature, but an expanded position at body temperature.

In one preferred embodiment, the valve of the stent is moved to a closed position on increasing the diameter of the stent from a collapsed position to an expanded position when the stent is suitably positioned in the body.

In particularly preferred embodiments the valve comprises at least one cantilever member as discussed above. Expansion of diameter of the stent e.g. on deployment of the stent, causes the valve to adopt the closed configuration.

In this embodiment, the cantilever member may be resiliently pivoted at a first end to the stent such

that on expansion of the diameter of the stent a second end of the cantilever member pivots to an extended position in which the material forming the valve and defining the aperture of the valve when in the open position is pulled such that the area of the aperture formed by the material is decreased.

More preferably the valve comprises two cantilever members which, on deployment of the stent, cause the diameter of the stent to expand from a collapsed configuration in which the valve portion of the stent is in an open position to an expanded configuration in which the valve is in a closed position. With the circular cross section increased flow through the stent is enabled and with the ellipsoidal cross section flow in the second direction is minimised.

In such an embodiment, the aperture formed by the resilient material is preferably pulled from a substantially circular cross section to a substantially ellipsoidal cross section, which, in use, restricts the flow of fluid from a second compartment toward a first compartment.

The diameter and length of the stent depends on its use. For example, the stent may be of suitable length to extend between the left ventricle of heart and coronary artery.

Preferably the stent is two to fifteen millimetres in diameter.

The stent may be constructed such that a number of stents may be positioned "end to end" to increase the effective length of the stent arrangment.

Thus, in one preferred embodiment the stent is resiliently deformable at at least one end to receive and enable connection with a second stent.

In an alternative embodiment the stent may be shaped at one or both ends to enable connection to a second stent.

The stent may comprise drug coatings or chemical and / or mechanical coatings such as a TEFLON ™ membrane to minimise stenosis.

As described above, stents of the present invention may be used to link or repair two cardiovascular compartments.

For example, stents of the invention may be used to link a coronary artery to the left ventricle of the heart.

Stents of the present invention may also be used in non coronary structures e.g. non coronary veins and / or arteries.

For example, the stents may be used to link a first portion of an ascending venous structure such as the saphenous vein and a second portion of the same

ascending venous structure. If the region between the first and second portions of the femoral artery is damaged or occluded, a stent of the invention may be located between the first and second portions to enable the movement of blood from the first portion to the second portion.

Thus in use, a stent of the present invention may be provided between a first and second portion of a vein e.g. a saphenous vein, to allow blood to flow from the first portion to the second portion, but restrict blood flow from the second portion to the first portion. Such an arrangement could be used to treat varicose veins.

In a second aspect of the present invention there is provided a method for treating a full or partial occlusion of a blood vessel comprising the step of

providing stent means wherein said stent means comprise at least one stent of the first aspect of the invention,

a first end of the lumen of the stent means being in communication with a cardiovascular compartment on one side of the occlusion,

the second end of the lumen of the stent means being in communication with a cardiovascular compartment on the other side of the occlusion allowing blood flow from the first side to the

second side of the cardiovascular compartment through the lumen of the stent means.

The cardiovascular compartments on each side of the occlusion may be in same the blood vessel in which the occlusion is present.

In alternative embodiments the cardiovascular compartments may be different compartments, for example the left ventricle of the heart and a coronary artery.

The stent means may comprise a single stent. Alternatively the stent means may comprise a plurality of stents longitudinally aligned to allow the flow of blood from a stent at a first end of the stent means to a stent at a second end of the stent means.

Preferably the stent means comprise a single stent of the first aspect of the invention.

In preferred embodiments the method further comprises the step of positioning the stent means between the compartments, increasing the diameter of the stent means from a reduced diameter in a collapsed position to an increased diameter in an expanded position.

In particularly preferred embodiments the method comprises the steps of

inserting the stent into position between a first cardiovascular compartment and a second cardiovascular compartment;

expanding the diameter of the stent such that the valve is moved to the closed position, but can move to the open position when fluid flows in a first direction from a first cardiovascular compartment to a second cardiovascular compartment.

According to a further aspect of the invention there is provided a method for treating varicose veins comprising positioning stent means comprising at least one stent of the first aspect of the invention in a vein or replacing all or part of a vein with stent means comprising at least one stent of the first aspect of the invention.

As above, stent means may comprise a plurality of stents longitudinally aligned to allow the flow of fluid from a stent at a first end of the stent means to a stent at a second end of the stent means.

As described above, in a preferred embodiment of a first aspect of the invention a stent comprising a valve comprising at least one cantilever member is provided. The use of such a valve is not limited to uses within the body. Accordingly, in a further independent aspect there is provided tube means, said tube means comprising a valve which comprises at least one cantilever member, having a first end

and a second end, said cantilever member being pivoted at said first end to the tube, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is open.

Tubes comprising such valves may be used to link a first cardiovascular compartment with a compartment in a cardiovascular device or *vice versa*.

In a further embodiment tubes comprising such valves may be used to link first and second compartments in a device to transport fluid, for example blood.

For example, such tubes comprising at least one cantilever member can be used in machines or devices used to move fluid, for example blood, such as dialysis machines.

A further independent aspect of the present invention is a device for the movement of fluid.

Preferably the fluid is blood.

The present invention will now be described, by way of example only, with reference to the accompanying figures in which;

Figure 1 is an illustration of an embodiment of a stent of the present invention extending from

the left ventricle of the heart into the coronary artery;

Figure 2 is an enlarged view of an embodiment of a stent of the present invention connecting the left ventricle of the heart to the coronary artery;

Figure 3 is an illustration of an embodiment of a stent of the present invention wherein a second end of the stent is in a closed position;

Figure 4 (A) is an illustration of an embodiment of a stent in a collapsed form, (B) is an illustration of an embodiment of a stent of the present invention in an expanded form;

Figure 5 is an illustration of an embodiment of a stent of the present invention where a second end of a stent is in an open position;

Figure 6 is an illustration of at least two embodiments of stents of the present invention aligned along their longitudinal axes such that blood can flow from the lumen of a first stent to the lumen of a second adjacent stent; and

Figure 7 is an illustration of stents according to an embodiment of the present invention aligned along their longitudinal length wherein the first stent has a shaped end to receive the

second stent and another stent is deformable to receive a stent inside one end.

As shown in figure 1, the coronary artery 10 is known to branch off the aorta 12 and be positioned along the external surface of the heart wall 14.

Following oxygenation of the blood, the oxygenated blood flows from the heart 16 into the aorta 12 and onto the rest of the body. Some of the oxygenated blood is circulated along the coronary artery 10 in order to oxygenate the muscles of the heart. In some individuals an occlusion is formed within the coronary artery due to plaque build up. These occlusions can lead to a variety of symptoms and diseases ranging from mild angina to heart attack.

In order to allow blood flow around the occlusion within the coronary artery and to at least partially restore the flow of oxygenated blood through the coronary artery, it is possible to bypass the blocked portion of the coronary artery by providing a stent 18 which extends from the left ventricle 20 of the heart into the coronary artery 10, as shown in figure 2. Location of the stent 18 as shown in figure 2 allows blood to flow unobstructed from the left ventricle 20 of the heart to the coronary artery 10.

Allowing blood flow past or around occlusions of the coronary artery 10 using a stent 18 is preferable to traditional bypass surgery in that the stent 18 may

be located and fitted using minimally invasive techniques. Generally the stents previously used to connect the left ventricle 20 of the heart to the coronary artery 10 are stents formed by hollow tubes comprising biocompatible material such as titanium alloys, nickel alloys or biocompatible polymers. These tubes may be provided and located between the left ventricle 20 of the heart and the coronary artery 10 in a collapsed position and when suitably located, expanded from a collapsed position to a fully expanded position, using an inflatable balloon catheter or other method.

Although such stents allow the flow of blood from the left ventricle 20 of the heart into the coronary artery, no artificial or mechanical means are present on conventional stents to restrict the backflow of blood.

As shown in figure 3, a stent of the present invention is provided with a synthetic valve 22, one example of the valve being a portion of flexible resilient material located at the second end 24 of the stent. This flexible resilient material is preferably integral with the rest of the stent.

The valve may be formed during manufacture of the stent, prior to insertion of the stent into the body.

Alternatively, as shown in the embodiment of the stent in figure 4, the valve can be created by the

pivotal movement of cantilever members during the movement of the stent from a collapsed position to an expanded position, while the stent is located in the body.

As shown in figure 4a, in this embodiment, in a collapsed position, the resilient material, held by two cantilever members 21, forms a substantially cylindrical aperture 28.

The cantilever members are conjoined to the stent at a first end only and from the rigid biocompatible metal portion 23 of the stent. On deployment (expansion of diameter) of the stent, the second ends of the cantilevers move away from each other to an extended position. This movement pulls the resilient material such that its cross sectional shape is changed from substantially circular to substantially ellipsoidal. The change in the cross sectional shape restricts the flow of blood in a second direction from the second compartment into the first compartment through the stent. Blood flow through the stent from a first compartment to a second compartment causes the material of the leaflets to be pushed such that the cantilever members resiliently move towards each other and the aperture of the valve becomes substantially circular in cross section. The area of the circular cross section is larger that the ellipsoidal cross section and blood can thus easily flow from the first compartment to the second compartment. During diastole, when blood is not being pushed from the

first compartment to the second compartment, the pressure of the blood on the material of the valve decreases. The second ends of the resilient cantilever members can again move away from each other and cause the valve material to form an ellipsoidal cross section.

It can be appreciated that if more than two cantilevers are used for example, three, four or five cantilevers, then on deployment, the cross sectional shape will not be elliptical, but substantially triangular, rectangular or pentacle shaped. Different shaped openings may be used as appropriate to restrict the flow of blood from the second compartment to the first compartment. In addition, different shaped openings can be chosen to minimise pressure on the arterial wall caused by the cantilever members.

In one embodiment, a valve formed from resilient material does not require expansion of the diameter of the stent to cause the resilient material to adopt the closed position. In this embodiment cantilever members are not required to pull the material of the valve to a closed position and the valve is manufactured in the closed position. Blood flow in a first direction from the first compartment towards the second compartment causes the resilient material to adopt an open position.

In addition to the cantilever members disclosed herein, different methods of urging the resilient

material to a closed position following expansion of a stent structure from a collapsed position can be envisaged.

During systole (contraction of the heart) the blood is pumped by the heart through the stent 18 from the first end 26 located at the left ventricle 20 of the heart towards the second end 24 of the stent located at the coronary artery. On contraction of the heart, the blood of the left ventricle of the heart is moved in a first direction through the stent causing the valve to move from an ellipsoidal shape (closed position) to an open (circular cross sectional shape) position.

In the closed position the ellipsoidal shape causes the area through which blood can flow from the second compartment to the first compartment to be reduced to 10% the area of the open position of the valve. The backflow of blood is thus reduced when blood is not being pumped through the stent from the first compartment to the second compartment.

Typically reflux of blood through the valve from the second compartment to the first compartment may be 25% that which would be expected if the valve is in the open position.

The movement of the resilient material in this manner, from an ellipsoidal shape (closed position) towards a circular shape (open position), increases the area of the aperture 28 through which the blood

can flow from the first compartment (in this case the left ventricle of the heart) into the second compartment (in this case the coronary artery) and allows the unobstructed flow of blood through the valve.

As the pressure of the blood flow through the valve in a first direction decreases, the resilient material is urged by the material (and in particular embodiments the cantilever members of the rigid portion of the stent) to cause the valve to adopt a resting position, wherein the aperture of the valve into the coronary artery forms an ellipsoidal shape. This change in shape of the aperture reduces the area of the aperture located at the second compartment and minimises the blood flow from the coronary artery into the left ventricle of the heart.

Movement of the stent from a collapsed position to an expanded position causes the stent to be gripped by the heart muscle. A flange or other projection may also be provided on the stent to aid location of the stent.

As shown in figures 6 and 7 at least two stents can be aligned along their longitudinal axes such that blood can be communicated from the lumen of a first stent to the lumen of a second adjacent stent. By aligning several stents together, blood may be moved from a first proximal position to a second distal position, either between two different

cardiovascular compartments such as the left ventricle of the heart and a coronary artery or within the same cardiovascular compartments such as a blood vessel.

By aligning a number of stents along their longitudinal axis it is possible to allow blood flow to be effected over a relatively large distance. In addition, as each of the stents comprise a valve, the stents more closely mimic the situation in actual veins preventing the backflow of blood and allowing blood to be moved upwards. An example of when the blood may be required to be moved upwards is in the leg of a patient when said patient is standing.

The valves present on each of the stents allow blood to be pushed through the valve on contraction of the heart, but minimise the backward movement of the blood during diastole. This allows blood to be moved up the leg and through the body.

To allow the stents to be conjoined to each other, a first end of a stent may be capable of deformation (as shown in figure 7 (30)) to allow a second stent to be partially inserted therein. Alternatively or additionally the stent may also be widened (figure 7 (32)) to allow ingress of a second stent as shown in figure 7.

It can be appreciated that various improvements and modifications can be made without departing from the

scope of the present invention. In particular it can be envisaged that the valve may be formed from at least two leaflets, which in a resting position are urged towards each other minimising blood flow from the second cardiovascular compartment into the first cardiovascular compartment. On movement of blood in a first direction through the stent, from the first compartment to the second compartment, these leaflets may be pushed apart from each other, enabling blood flow from the first compartment into the second compartment. During diastole the two leaflets of the valve will be urged towards each other due to the resilience of the material. Alternatively, different methods may be used to align the stents along their longitudinal length such as providing junction means.

Claims

1. A cardiovascular stent comprising:
a generally tubular body, and
a synthetic one-way valve capable of moving from a first open position to a second closed position, wherein, in use, movement of fluid in a first direction through the stent causes the valve to adopt the open position and movement of fluid in a second opposite direction causes the valve to adopt the closed position.

2. A cardiovascular stent as claimed in claim 1 wherein the valve is formed from resilient material.

3. A cardiovascular stent as claimed in claim 2 wherein the valve is constructed such that, in use, movement of fluid in the first direction through the stent urges the resilient material of the valve to adopt a configuration in which the aperture defined by the material is substantially circular in cross-section thereby enabling increased fluid to flow through the valve and thus through the stent.

4. A cardiovascular stent as claimed in claim 2 or 3 wherein the valve comprises two leaflets formed from resilient material and wherein, in use, when fluid is flowing in the second direction through the stent or when no fluid is flowing through the stent, the leaflets are

urged towards each other such that the passage of fluid is minimised.

5. A cardiovascular stent as claimed in any one of the preceding claims, wherein the valve comprises at least one cantilever member having a first end and a second end, said cantilever member being pivoted at said first end to the stent, the cantilever member being resiliently pivotable from a first extended position in which the valve is in a closed position to a second position in which the valve is in the open position.

6. A cardiovascular stent as claimed in claim 5 wherein the valve comprises two cantilever members.

7. A cardiovascular stent as claimed in any one of the preceding claims wherein the stent is constructed such that it can be expanded in diameter from a "collapsed" configuration to an "expanded" configuration, wherein in the collapsed configuration, the stent is of narrower diameter than in the expanded configuration.

8. A cardiovascular stent as claimed in claim 7 when dependent on claim 5 or claim 6 wherein on expansion of the diameter of the stent, the second end of the cantilever member pivots to an extended position in which the material

forming the valve and defining the aperture of the valve when in the open position is pulled such that the area of the aperture formed by the material is decreased.

9. A cardiovascular stent as claimed in any one of the preceding claims wherein the stent is resiliently deformable at one or both ends to receive and enable connection with a second stent.

10. A cardiovascular stent as claimed in any of one of the preceding claims wherein the stent is shaped at one or both ends to enable connection to a second stent.

11. A cardiovascular stent as claimed in any one of the preceding claims for linking a coronary artery to the left ventricle of the heart.

12. A cardiovascular stent as claimed in any one of claims 1 to 10 for linking a first portion of an ascending venous structure and a second portion of the same ascending venous structure.

13. A method for treating a full or partial occlusion of a blood vessel comprising the steps of:

providing stent means wherein said stent means comprise at least one stent as claimed in claims 1 to 12, a first end of the lumen of the

stent means being in communication with a cardiovascular compartment on a first side of the occlusion,

the second end of the lumen of the stent means being in communication with a cardiovascular compartment on the other side of the occlusion and allowing blood flow from the first side of the occlusion to the other side of the cardiovascular compartment through the lumen of the stent means.

14. A method as claimed in claim 13 wherein the stent means comprises a plurality of stents longitudinally aligned to allow the flow of blood from a stent at a first end of the stent means to a stent at a second end of the stent means.

15. A method as claimed in claim 13 or claim 14 further comprising the step of increasing the diameter of the stent from a reduced diameter in a collapsed position to an increased diameter in an expanded position.

16. A method for treating varicose veins comprising the step of:

positioning stent means comprising at least one stent as claimed in claims 1 to 12 in a vein.

17. A method for treating varicose veins comprising the step of:

replacing at least a part of a vein with stent means comprising at least one stent of the first aspect of the invention.

18. Tube means comprising a tubular portion and a valve, said valve comprising at least one cantilever member having a first end and a second end, said cantilever member being pivoted at said first end to the tubular portion, the cantilever member being resiliently pivotable from a first extended position in which the valve is in the closed position to a second position in which the valve is in the open position.

19. Tube means as claimed in claim 18 wherein in moving from the closed position to the open position the aperture of the valve is moved from being ellipisoidal to substantially circular.

20. A device for moving fluid comprising a tube as claimed in claims 18 or 19.

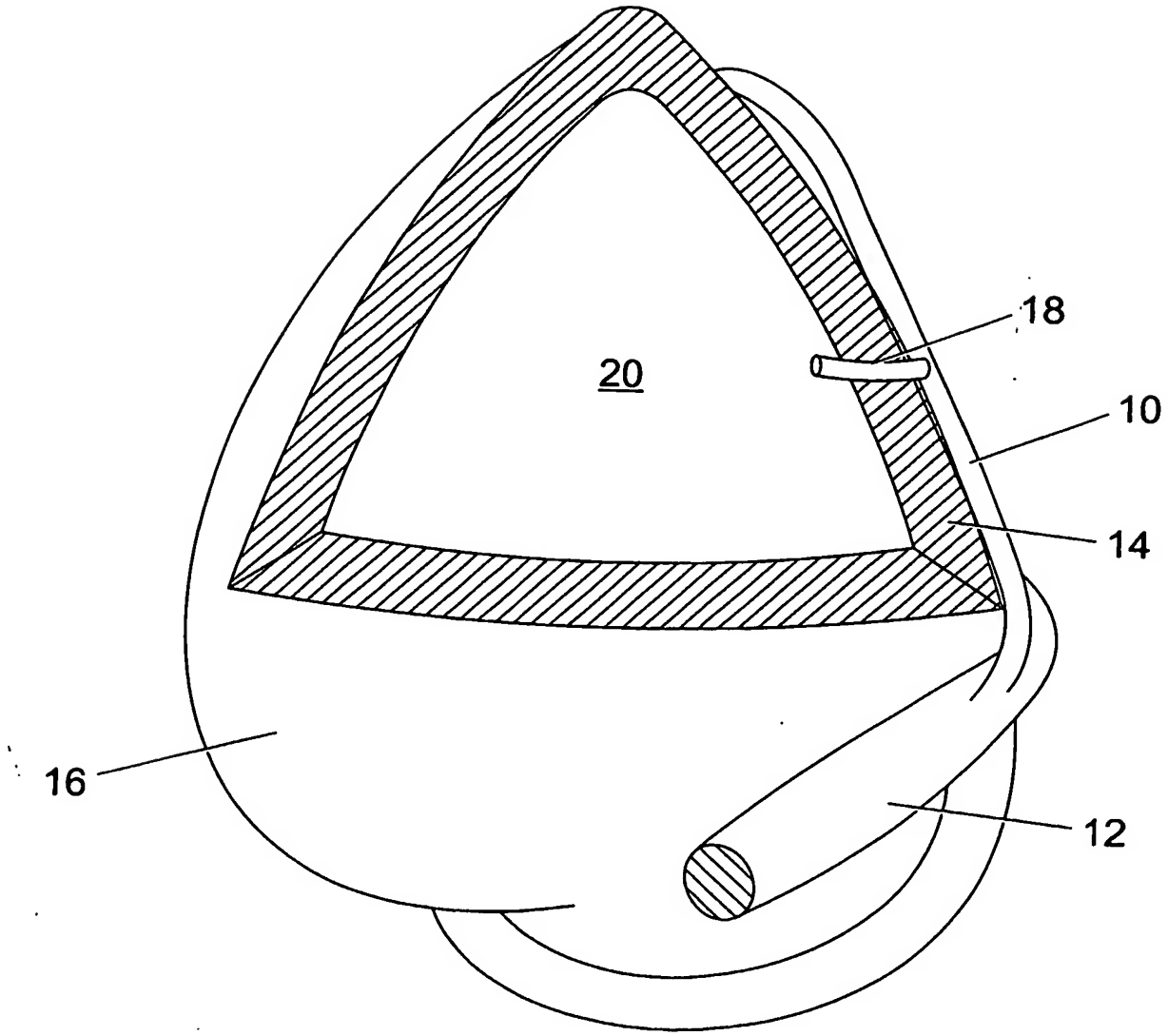


Fig. 1

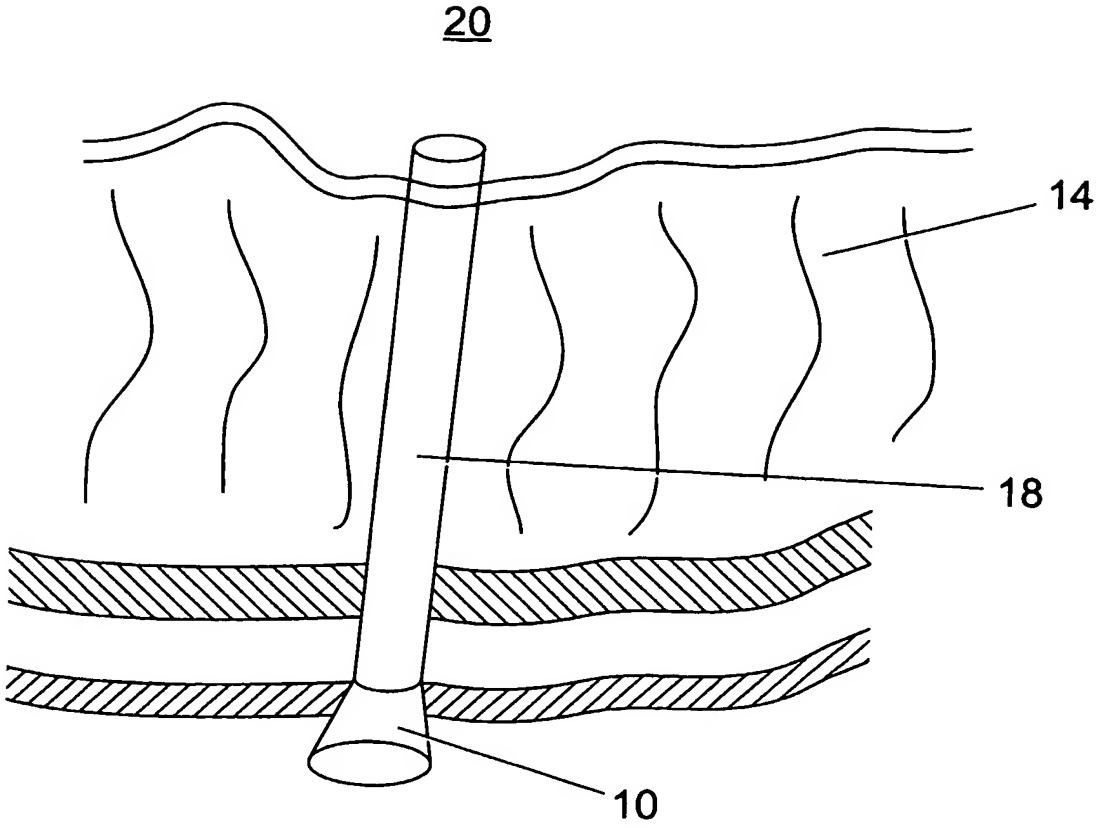


Fig. 2

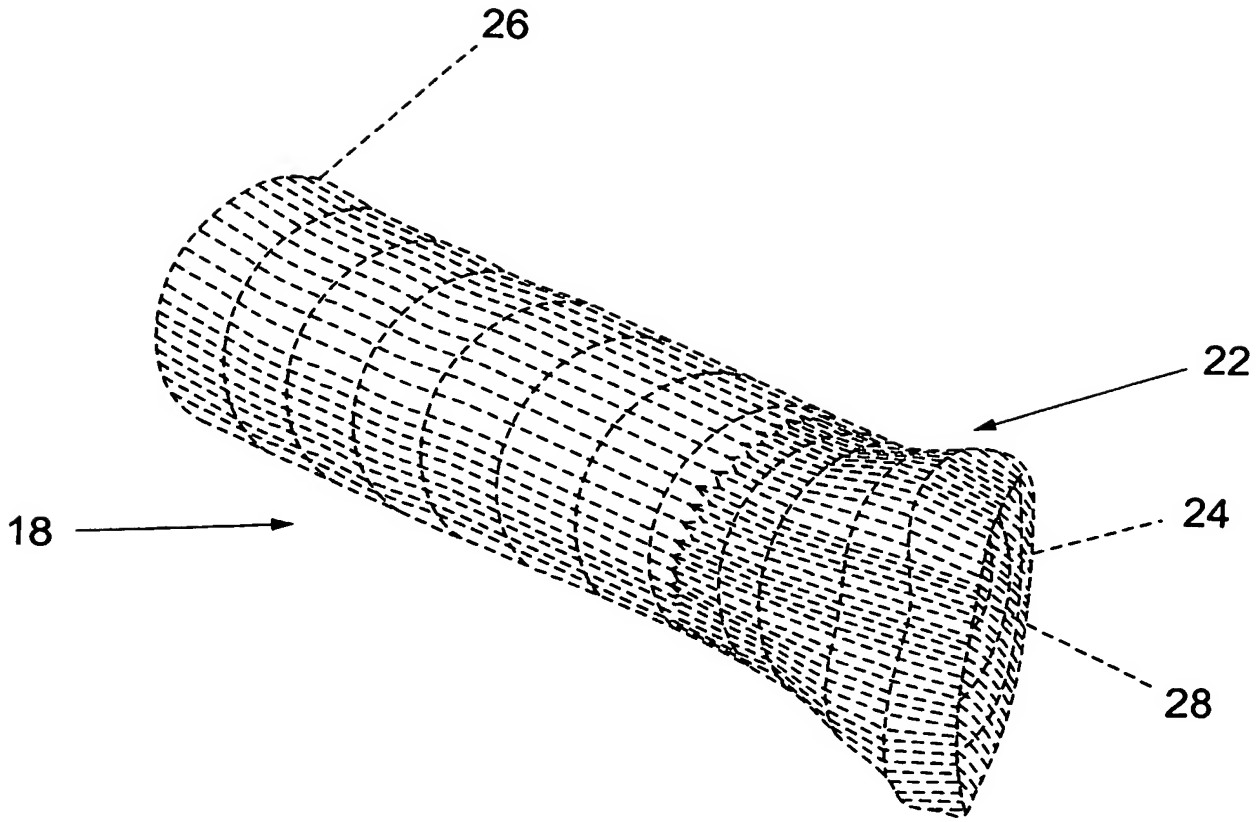


Fig. 3

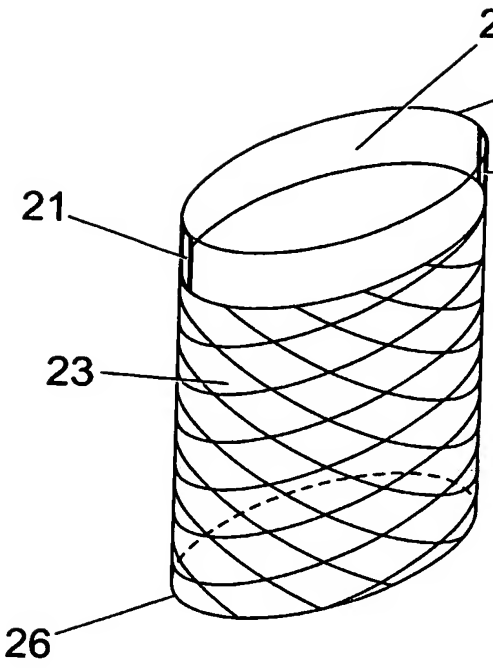


Fig. 4a

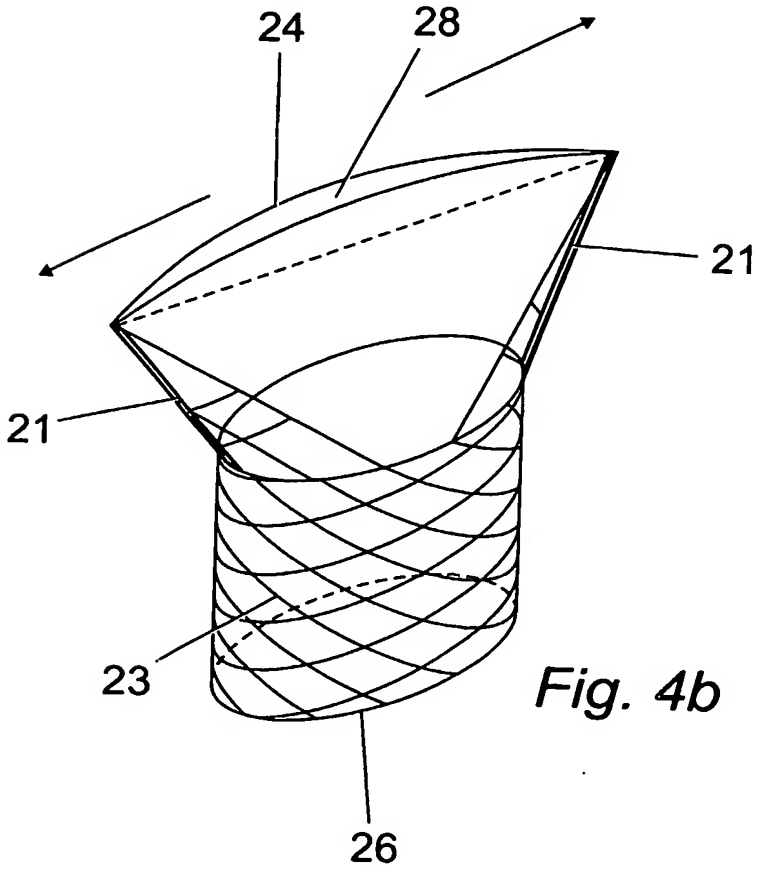


Fig. 4b

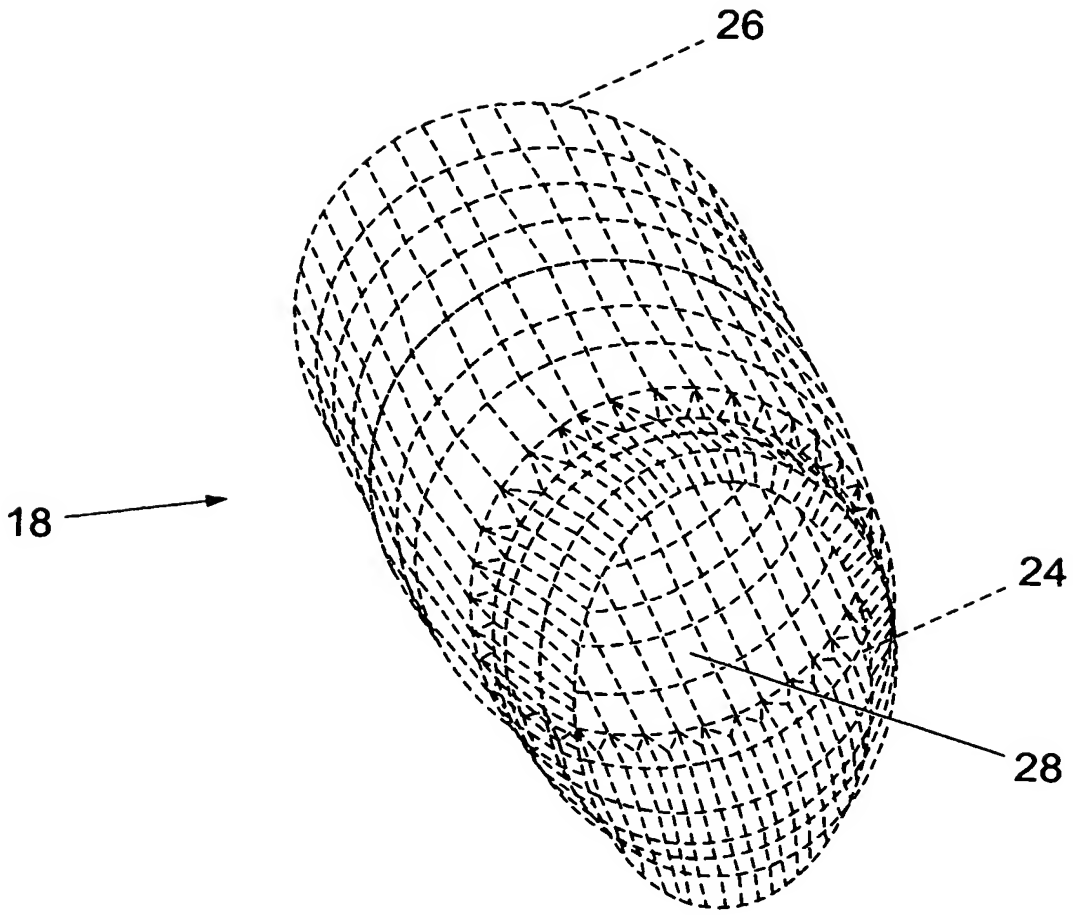


Fig. 5

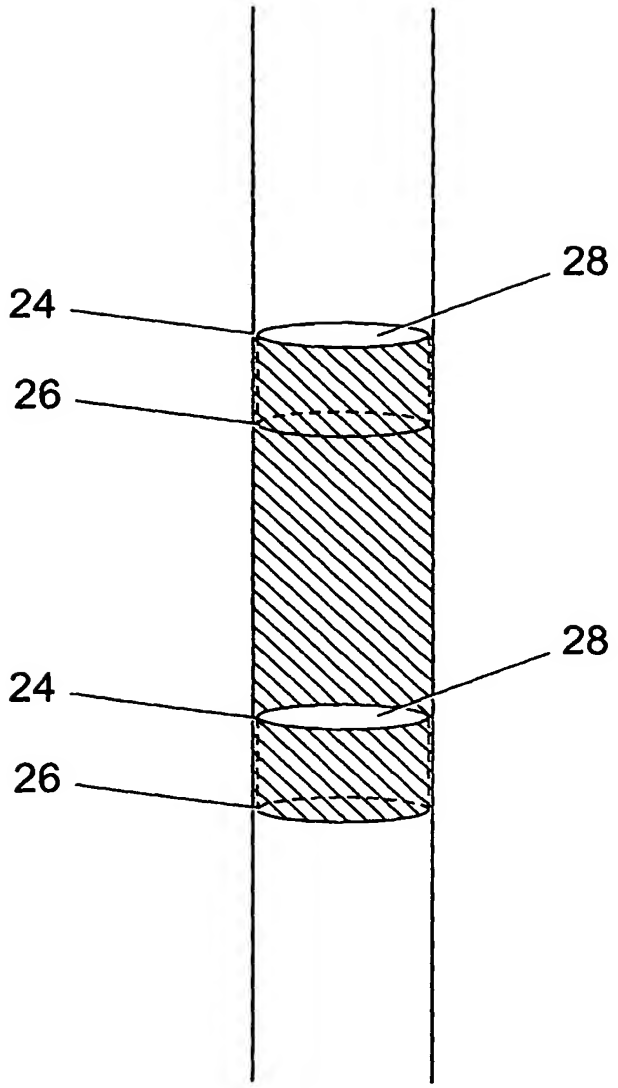


Fig. 6

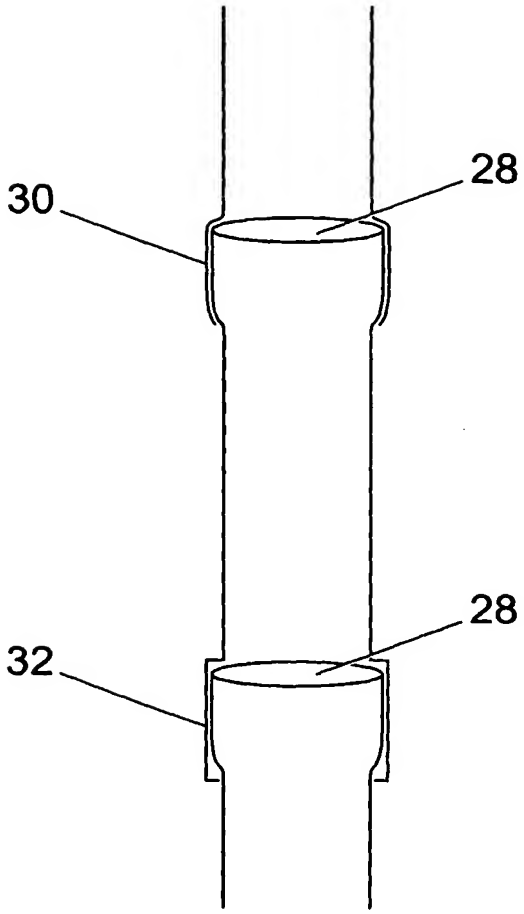


Fig. 7

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(71) Applicant *(for all designated States except US)*: **AORTECH INTERNATIONAL PLC** [GB/GB]; Phoenix Crescent Business Park, Bellshill ML4 3NJ (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **BEITH, Jason** [GB/US]; Edwards Lifescience, On edwards Way, Irvine, CA 92614 (US).

(74) Agent: **MURGITROYD & COMPANY**; Scotland House, 165-169 Scotland Street, Glasgow G5 8PL (GB).

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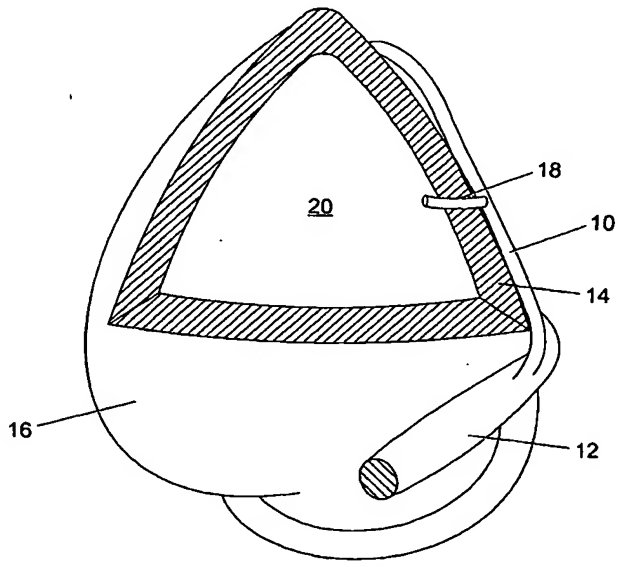
(54) Title: BLOOD REGULATION DEVICE




(57) Abstract: The present invention relates to a cardiovascular stent (18) including a generally tubular body and a synthetic valve (22) capable of moving from a first open position to a second closed position wherein, in use, the stent is located between a first compartment and a second compartment and movement of blood in one direction causes the valve to move to an open position and movement of blood in a second opposite direction causes the valve to move to a closed position. In particular a stent is provided to connect the left ventricle of the heart to a coronary artery which allows blood to flow through the stent from the left ventricle of the heart into a coronary artery, but minimises reflux of blood from the coronary artery to the left ventricle of the heart.

WO 2004/019814 A3

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# INTERNATIONAL SEARCH REPORT

national Application No
PCT/GB 03/03810

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br><br>Y<br>A | US 2002/165606 A1 (SANTAMORE WILLIAM ET AL) 7 November 2002 (2002-11-07)<br>paragraph '0034!<br>paragraph '0002!<br>paragraph '0009! - paragraph '0011!<br>paragraph '0028!<br>paragraph '0038!<br>paragraph '0042! - paragraph '0045!<br>figures 1A-4 | 1-7,11,<br>12,18,20<br>19<br>8-10 |
| Y | US 4 759 758 A (GABBAY SHLOMO)<br>26 July 1988 (1988-07-26)<br>column 4, line 1 - line 30<br>figures 7,9,10 | 19 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 11 May 2004 | 19/05/2004 |

| Name and mailing address of the ISA | Authorized officer |
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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Amaro, H |

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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 03/03810

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-17
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 03/03810

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